

REMARKS

I. Oath/Declaration

The Examiner has asserted that the Declaration submitted with the present application on February 9, 1999 is defective because it does not identify the post office address of each inventor. However, Applicants have included 1) the street address in the box entitled "Residence", 2) the city, state and zip code in the box entitled "Post Office Address", and 3) the country of residence in the box entitled "Citizenship." Therefore, this information is included in the Declaration. According to M.P.E.P. 605.03, the object of requiring the post office address is to enable the Office to Communicate directly with the Applicant. As the residence, post office address and country of residence are provided in the present Declaration for each inventor in accordance with the provisions of 37 CFR 1.63(a)(3), Applicants respectfully request that the Examiner's objection be withdrawn.

I. Rejection under 35 U.S.C. §112, second paragraph

The Examiner has rejected Claims 1 to 21 under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Examiner points out that Claims 1, 10 and 19 are not in proper Markush form. Applicants amend Claims 1, 10 and 19 as requested by the Examiner. Claim 16 does not contain a period. Claims 16, 18 and 22 recite the limitation of a "nib-type" and is rendered indefinite by the use of the word "type." Applicants amend Claims 16, 18 and 22 to correct punctuation and delete the adjective, "nib-type", describing the eyeliner pen as requested by the Examiner. Finally, the Examiner points out that Claims 5 and 14 lack antecedent basis for the limitation of "ammonium acrylate." Ammonium acrylate is a type of acrylate (acrylic acid ester) derived polymer described in Claims 1 and 10. Claims 5 and 14 are amended to provide sufficient antecedent basis. No new matter is added.

II. Rejection under 35 U.S.C. §102(b)

The present invention is based on the combination of the water soluble organic pigment with the acrylic or methacrylic acid derived polymer or copolymer. In the present Office Action, the Examiner asserts that the present invention is anticipated by several references. Each reference cited by the Examiner, however, fails to anticipate the present invention because they each fail to disclose a water soluble organic pigment. Each reference is addressed in turn below.

A. The Murui ('031) Reference

Claims 1 to 4, 6, 7, 9 to 13 and 15 to 21 are considered to be anticipated by Murui et al. (U.S. Pat. No. 4,423,031, hereinafter referred to as "the '031 reference"). According to the Examiner, the compositions in Table 2 of the '031 reference comprise 10% of an organic pigment. However, the pigment (a mixed lake) disclosed in Table 2 is not soluble in water, and the '031 reference fails to disclose a water soluble organic pigment.

In general, lakes are made by extending a salt on a substrate, and are insoluble pigments, like inorganic pigments. This definition is pursuant to 21 C.F.R. 82.51, attached herewith, wherein FD&C lakes are defined by their process of manufacture of extending on a substratum of alumina, a salt prepared from one of the certified water-soluble straight colors by combining the colorant with the basic radical aluminum or calcium. Therefore, lakes, as they are extended on an aluminum substrate, are particulate in nature, i.e., insoluble pigments, and are not the water soluble organic pigments of the present invention. In support of this, Applicants also submit herewith a copy of a reference disclosing that organic lakes are not water soluble. FD&C Yellow No. 5 Aluminum Lake, for example, is described in the CTFA Monographs (6th Edition 1995) at p. 386 as an insoluble pigment. Thus, the '031 reference fails to disclose a water soluble organic pigment and fails to, therefore, anticipate the present invention.

B. The Remz ('571) Reference

Claims 1 to 4, 6 to 13, 15, 17 and 19 to 21 are considered by the Examiner to be anticipated by Remz et al. (U.S. Pat. No. 4,712,571, hereinafter referred to as "the '571 reference"). As previously mentioned above, the compositions of the present invention comprise an acrylic or methacrylic acid derived polymeric or copolymeric component in combination with at least one water soluble organic pigment. The '571 reference also fails to disclose a water soluble organic pigment.

According to the Examiner, the nail polish compositions of the '571 reference comprise a methyl-butyl methacrylate copolymer and an organic pigment such as FD&C yellow 5. At column 2, lines 33 to 35, the '571 reference discloses a list of FDA certified pigments which includes FD&C Yellow 5. However, at column 2, lines 18 to 27, suitable pigments are described as being

substantially insoluble in solvents, essentially free from a tendency to bleed, and having an average particle size such that satisfactory dispersing is insured. Therefore, one of ordinary skill in the art would understand that the pigments are not water soluble. In addition, at column 2, lines 40 to 50, the '571 reference discloses that the pigments are ground in a mill base. The mill base, as described in column 2, lines 57 to 61, comprises a water-insoluble protective colloid capable of preventing flocculation of the pigment particles. Again, one of ordinary skill in the art would understand that the pigment particles of the '571 reference are not water soluble.

Further evidence demonstrating that the pigments of the '571 reference are not water soluble is found in Examples 1 to 12, and Table 3 wherein the '571 reference only discloses lakes in conformance with the other previously mentioned disclosures regarding pigments. Although the nail polish formulations provided in Tables 1 and 2, like the disclosure of FDA certified pigments in column 2, lines 33 to 35, do not list lakes, the footnotes for each of the pigments in Tables 1 and 2 refer back to the pigment pastes prepared in Examples 1 to 12 which include lakes. Therefore, the pigments in the tables and the examples are lakes. As previously discussed, with respect to the '031 reference, lakes are not water soluble organic pigments. In addition, the formulations in Tables 1 and 2 are directed to forming pigment chips which are, like particles, inherently not water soluble. Therefore, all of the Examples and Tables of the '571 reference incorporate insoluble pigments, and fail to disclose the water soluble organic pigments of the present invention.

One of ordinary skill in the art would understand that the only pigments disclosed in the '571 reference are insoluble pigments and lakes (which are not water soluble). Under 35 U.S.C. § 102, in addition to requiring that each and every element of the claimed invention be disclosed in a prior art reference, anticipation requires that the prior art reference be enabling, thus placing the allegedly disclosed matter in the possession of the public. *Akzo N.V. v. U.S. International Trade Commission*, 1 USPQ2d 1241, 1245 (CAFC 1986) (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984), and *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964)). Because the '571 reference only discloses insoluble pigments, the '571 reference does not place compositions containing a water soluble organic pigment in the possession of the public, and therefore, the present invention is not anticipated by the '571 reference.

C. The Alwattari ('072) Reference

Claims 1 to 7, 9 to 14, and 19 to 22 are according to the Examiner anticipated by a third reference, Alwattari et al. (U.S. Patent No. 5,874,072, hereinafter referred to as the '072 reference.) The Examiner asserts that the '072 reference discloses a mascara comprising ammonium acrylate and organic pigments. However, specifically, at column 6, lines 7 to 8, the organic pigments are organic lake pigments. As discussed previously, lakes are not water soluble. In addition, the '072 reference at column 5, line 65 to column 6, line 9, discloses that pigments are contained in the solids component of the '072 compositions. Based on the disclosure of the '072 reference regarding its pigments, and like the two previously cited references, one of ordinary skill in the art would understand that the pigments of the '072 reference are not water soluble, whereas, the present invention includes water soluble organic pigments.

Anticipation, based on the '072 reference, is not found because the '072 reference fails to expressly disclose the element of the water soluble organic pigment of the present invention. Absence from the cited reference of any claimed element negates anticipation. *Minnesota Mining and Manufacturing Co. v. Johnson & Johnson Orthopedics Inc.*, 24 USPQ2d 1321, 1332 (CAFC 1992) (cited reference fails to provide exact limitations specified in claims). However, a prior art reference may anticipate when the claim limitation, while not expressly found in the reference, is nonetheless inherent in it. *Atlas Powder Co. v. IRECO Inc.*, 51 USPQ2d 1943, 1946 (CAFC 1999)(citations omitted). Under the principles of inherency, if the prior art necessarily includes the claimed limitations it anticipates. *Id.*

The '072 reference fails to inherently disclose water soluble organic pigments as included in the present invention. Although in column 6, lines 21 to 31, specific organic pigments and lakes of various D&C pigments are provided, the processing steps of the '072 reference, at column 7, lines 6 to 48, disclose that pigments are added to the oil phase with other solid materials that are hydrophobic such as for example, fillers. Specifically, the processing directions for oil-in-water emulsions, at column 7, line 12, discloses that pigments are added to the heated waxes and fats along with any other oil dispersible or oil soluble components. Similarly, the water-in-oil emulsions are prepared by dispersing pigments, and any other hydrophobic materials, to the lipophilic phase. This is disclosed in the '072 reference at column 7, lines 39 to 40. The teaching of dispersing the pigment indicates that the pigment is not solubilized. In addition, Applicants

attach herewith the definition of D&C lakes according to 21 C.F.R. 82.1051 wherein D&C lakes are defined to be made by extending a salt, which is not necessarily water soluble, as the salt extended in FD&C lakes are according to 21 C.F.R. 82.51, on a substrate. Thus, the '072 reference discloses that its pigments are included as a solid in the oil phase of the composition, and therefore, one of ordinary skill in the art would understand that the pigments of the '072 reference, as they are necessarily dispersible, are not the water soluble organic pigments of the present invention.

As the '072 reference does not inherently or expressly disclose the water soluble organic pigments of the present invention, anticipation cannot be found. Accordingly, Applicants request that the rejection under 35 U.S.C. §102(b) be withdrawn.

III. Unobviousness

A. The '031 and the '072 References

The Examiner has rejected Claims 1 to 7, and 9 to 22 under 35 U.S.C. §103(a) as being unpatentable over the '031 reference and the '072 reference. Specifically, the Examiner asserts that the '031 reference fails to teach ammonium acrylate as described in the present claims. The '072 reference, according to the Examiner, teaches a composition comprising ammonium acrylate, although it does not teach a flow-through applicator or eyeliner pen having a nib as described in the present amended claims. However, the Examiner incorrectly reasons that it is well known that mascara is applied using a brush applicator and this method is considered to be equivalent to a flow-through applicator. The characteristics of compositions used in flow-through applicators differ from mascara compositions used with a brush applicator. The flow-through applicator or pen having a wick can get clogged if the composition does not flow smoothly through the wick. As a result the composition cannot be retrieved for application. This is unlike mascara brush applicator systems where even if the mascara composition does not maintain a smooth texture, the clumpy composition can still be applied using the brush. It is not rendered completely useless by a complete blockage.

The Examiner states that it would have been obvious to one of ordinary skill in the art to use the ammonium acrylate taught in the '072 reference in the compositions of the '031 reference. Further, the Examiner believes that one of ordinary skill in the art would have a reasonable

expectation of providing an improved eye makeup composition that is applied with a nib-type applicator. Motivation, according to the Examiner, is found in the desire to make an eye makeup composition with improved wear that can be easily applied and removed with soap and water. However, these cited references fail to teach or suggest a water soluble organic pigment.

For reasons further elaborated upon above, neither the '072 reference nor the '031 reference teaches or suggests the water soluble organic pigments of the present invention. Obviousness is tested by "what the combined teachings of the references would have [taught or] suggested to those of ordinary skill in the art." *In re Fine*, 5 USPQ2d 1596, 1599 (CAFC 1988) (citing *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981)). Absent some teaching or suggestion to support the combination, obviousness cannot be established by the combination of prior art references. *Id.* (citations omitted). And, "teachings of references can be combined only if there is some suggestion or incentive to do so." *Id.* With respect to the present invention, there is no motivation or incentive provided in the cited references to incorporate the water soluble organic pigment of the present invention as use of such is not recognized in either cited reference, and the Examiner's line of reasoning fails to remedy this defect. If the only suggestion for the combination of the cited references follows from the claimed invention and not from the prior art, then a *prima facie* case of obviousness is not made. *Ex parte Levengood*, 28 USPQ2d 1300, 1301 (BdPatApp&Int 1993).

B. The '031, the '072 and the '571 References

The Examiner asserts that in addition to the previously addressed cited references, the '031 reference and the '072 reference, in further view of the '571 reference renders Claims 1 to 7 and 19 to 22 unpatentable under 35 U.S.C. §103(a). The Examiner asserts that the '031 reference generically teaches pigments, and that the '072 reference teaches D&C pigments. Further, according to the Examiner, the '571 reference teaches specific pigments and teaches the equivalency between D&C and FD&C pigments. Therefore, the Examiner reasons that one of ordinary skill in the art would prepare the compositions of the '031 reference, using the ammonium acrylate of the '072 reference, and substitute FD&C pigments of the '571 reference based on the equivalency between FD&C and D&C pigments. In conclusion, the Examiner asserts that there is a *prima facie* case of obviousness. However, Applicants believe that a *prima facie* case of

obviousness has not been made because none of the cited references, alone or in combination, teach or suggest a water soluble organic pigment.

The '031 reference does not teach or suggest a water soluble organic pigment. Contrary to the assertion made by the Examiner, the '031 reference does not generically teach pigments. At column 4, line 2, the '031 reference teaches, in a parenthetical, that pigments are an example of a type of component that can be incorporated into eye makeup preparations. The parenthetical also includes oils, which unlike pigments, is later on in the '031 reference generically disclosed. In the context of the '031 reference in its entirety, pigments are specifically defined to be finely divided inorganic pigments. In contrast, oils are generally defined, at column 5, line 67 to column 6, line 6, to be any oils incorporated into conventional eye makeup preparations. At column 5, lines 35 to 41, the specific definition of "pharmaceutically acceptable finely divided inorganic pigments" as used in the '031 reference is provided. Therein, it is defined as any of the inorganic pigments which are incorporated into conventional eye makeup preparations, and examples are provided. Thus, it can be seen that a generic disclosure of pigments is not provided by the '031 reference, but rather a specific type of pigment, namely the inorganic pigment is generically provided for in the '031 reference. Furthermore, the '031 reference does not teach or suggest a water soluble organic pigment. The Examiner also refers to the tables at columns 9 and 10 as support for teaching organic pigments. However, as discussed above with respect to the §102 rejection, the examples and tables of this reference also fail to teach or suggest a water soluble organic pigment of the present invention.

Second, review of the definitions of FD&C and D&C pigments indicates that they are not equivalent. As previously discussed above in the §102 argument, according to 21 C.F.R. 82.51 and 82.1051, FD&C Lakes and D&C Lakes are defined. FD&C lakes are made by extending a salt on a substratum of alumina, while D&C lakes are made by extending a salt on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or a combination of these substrates. In addition, FD&C pigments are prepared from water-soluble colors while D&C pigments are not necessarily based on water-soluble colors. However, even if they were, the D&C and FD&C pigments taught or suggested in the compositions of the cited references are water-insoluble, and therefore, are not the water soluble pigments of the present invention.

In order to establish a *prima facie* case of obviousness, the Examiner must present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. *Ex parte Levengood*, 28 USPQ2d 1300, 1301 (BdPatApp&Int 1993); see also, *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985)). Obviousness is not found when considering the references in less than their entireties. "There must be something in the prior art as a whole to suggest the desirability, and thus, the obviousness of making the combination" that leads to the present invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985) (quoting *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984)). With respect to the present invention the individual references, and therefore, the combination of the references, does not address the use of water soluble organic pigments. The cited references only teach inorganic pigments or water insoluble pigments. There is no teaching or suggestion, and likewise, no motivation or desire to modify the pigments of the cited references to the water soluble organic pigment of the present invention, and therefore, a *prima facie* case of obviousness has not been made.

C. The '031, the '072 and the '277 References

Finally, the Examiner cites the '031 reference, the '072 reference and the '277 reference against Claim 8 under 35 U.S.C. §103(a). According to the Examiner, one of ordinary skill in the art would prepare the composition of the '031 reference, using the ammonium acrylate of the '072 reference and substituting the FD&C pigments of the '277 reference because of their equivalency with D&C pigments. Therefore, the Examiner asserts that a *prima facie* case of obviousness has been made. However, as elaborated upon above, the '031 reference teaches finely divided inorganic pigments and does not generically teach pigments. Thus, a *prima facie* case obviousness is not made because none of the cited references, including the '277 reference, alone or in combination, teaches or suggests a water soluble organic pigment in combination with the polymeric component of the present invention.

The '277 reference discloses at column 1, lines 58 to 62, water-soluble organic pigments. However, the 277 reference fails to teach or suggest the polymeric component of the present invention. As discussed in the present specification at page 4, lines 15 to 17, the long-wearing compositions are based on the water soluble organic pigments in combination with an acrylic or methacrylic acid derived polymer or copolymer. The water-soluble organic pigments of the '277 reference, in contrast to the present invention, are combined with a combination of polyvinyl pyrrolidone and polyvinyl alcohol. Thus, the '277 reference fails to disclose the polymeric component of the present invention.

In combination with the '031 reference and the '072 reference, the '277 reference still fails to teach or suggest the present invention because there is no motivation to incorporate the water-soluble pigments of the '277 reference in either of the '031 reference or the '072 reference. The '277 reference, at column 1, lines 23 to 31, teaches that conventional lipliner compositions employ a wax or anhydrous (oil) base which is relatively viscous and would cause clogging of the wick. Further, according to the '277 reference, such lipliners do not hold the lipline because the wax or anhydrous base lipliners mix with the oil and sweat of the skin or the lip which causes the lipliner composition to solubilize. Therefore, the '277 reference teaches away from using the oil base compositions of the '072 reference, and one of ordinary skill in the art would not be motivated to combine the references.

The '072 reference teaches that its pigments are part of the solids component of its compositions, and that the pigments are dispersed in an oil phase. One of ordinary skill in the art would not expect water-soluble organic pigments to be compatible with the compositions of the '072 reference. Rather, one skilled in the art would expect to encounter problems with fading, bleeding, and running of the color due to the use of the water soluble organic pigment. As mentioned in the present specification, despite the increased desire to use organic pigments in compositions, most, if not all, organic pigments have a tendency to bleed or fade. Further, water soluble organic pigments have a tendency to run after they are applied to the skin. Attempts to stabilize water soluble organic pigments have merely resulted in specific solvent systems for specific pigments. This is discussed in the present specification at pages 1 to 2. Thus, one of ordinary skill in the art would not expect to be able to take a water soluble organic pigment as taught in the '277 reference and use it in the compositions described in the '072 reference.

One of ordinary skill in the art would not combine the teachings of the '031 reference with that of the '277 reference. The pigment of the '031 reference is incorporated in the water phase, and the pigment is inorganic and water insoluble. One of ordinary skill in the art would not be motivated to substitute the water-soluble pigment of the '277 reference, protected by the combination of PVP and polyvinyl alcohol, for the finely divided inorganic pigment of the '031 reference as it does not contain the same protective polymeric system. The '031 reference, at column 3, lines 61 to 64, teaches that changes in the polymeric system affect the water-resistant properties of the composition. One of ordinary skill in the art would not reasonably expect success substituting the inorganic pigment of the '031 reference with the water-soluble pigment of the '277 reference without compromising the desired water-resistance, stain-proof, and rub-proof qualities because they use different polymeric systems.

Finally, one of ordinary skill in the art would not combine the teachings of the '072 reference and the '031 reference with the '277 reference as each of the cited references employs different polymeric systems. Each polymeric system comprises a different combination of polymers, as well as different pigments. Based on the teachings and suggestions of these cited references, one of ordinary skill in the art would not expect to be able to use different types of pigments in different polymeric systems and reasonably expect similar results. Prior art references must be read as a whole and consideration must be given to references that diverge and teach away from the claimed invention. *Akzo N.V. v. U.S. International Trade Commission*, (CAFC 1986) 1 USPQ2d 1241, 1246 (citing *W.L. Gore & Associates, Inc. v. Garlock*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. den.*, 469 U.S. 851 (1984)). Individual elements cannot be plucked from different prior art references and then pieced together using the claimed invention as hindsight to guide the way. *Id.* (citing 721 F.2d at 1552, 220 USPQ at 312).

The combination of the cited references fails to teach or suggest the present invention of a water soluble organic pigment in combination with a polymeric component comprising an acrylic or methacrylic acid polymer or copolymer. Therefore, for the reasons stated above, Applicants submit that the claims of the present application satisfy the requirements of 35 U.S.C. §103(a).

CONCLUSION

Accordingly, the claims, as amended, are believed to be in condition for allowance, and issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

Estelle J. Tsevdos

June 15, 2000

By: Mary C. Weaver Reg. No. 30,333

Estelle J. Tsevdos, Reg. No. 31,145
Kenyon & Kenyon
One Broadway
New York, NY 10004
(212) 425-7200